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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

May 12, 2003

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref: 2003-DAL-WL-10

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. William J. Przybyla
Chief Executive Officer and Vice President
Montco Precision Machines, Inc.
1803 Baker Drive
P.O. Box 358
Tomball, Texas 77375

Dear Mr. Przybyla:

Our review of information collected during an inspection of your firm located at the above-referenced address on March 7 through 20, 2003, revealed that your firm manufactures E-Z Align™ CO_2 Laser Couplers and accessories (e.g., laser adapter with integrated lens housings, lens housings, connectors, and suction probe). These products are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, you were issued a Form FDA-483 which delineated a number of significant GMP inspectional observations which include, but are not limited to, the following (note that some of these GMP observations are repeat observations from the previous inspection concluded on June 29, 2001):

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization [21 CFR 820.20]. For example:

   a) Your firm has not documented the appointment of a management representative [21 CFR 820.20(b)(3)] [FDA-483 Item 1(a)], a repeat observation from the June 29, 2001 inspection; and

b) Your firm has not established and maintained procedures for management reviews and quality audits [21 CFR 820.20(c)] and [21 CFR 820.22], respectively [FDA-483 Items 1(b) and 2], repeat observations from the June 29, 2001 inspection; and

c) Your firm has not conducted quality audits since June, 2001 [21 CFR 820.22], a repeat observation from the June 29, 2001 inspection.

2. Failure to establish and maintain procedures for implementing corrective and preventive action to include all the requirements as required by CFR 820.100(a)(1) through (a)(7) and (b) [FDA-483 Item 4]. This deviation is a repeat observation from the June 29, 2001 inspection.

3. Failure to establish and maintain procedures for investigating the cause of nonconformities relating to product, processes, and the quality system [21 CFR 820.100(a)(2)] [FDA-483 Item 5]. For example, it is difficult to investigate the cause or trend of nonconformities because your firm did not maintain records of production rejects. This deviation was a repeat observation from the June 29, 2001 inspection.

4. Failure to establish and maintain process control procedures to include documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production [21 CFR 820.70(a)(1)] [FDA-483 Item 7]. For example, your firm has not established procedures for the assembly or making of laser couplers.

5. Failure to establish and maintain acceptance procedures to include documentation of acceptance test results of in-process product [21 CFR 820.80(c)] [FDA-483 Item 8]. For example, your firm inspected every [redacted] or [redacted] production unit but did not document the acceptance test results.

6. Failure to establish and maintain procedures to include documentation of disposition of nonconforming product [21 CFR 820.90(b)][FDA-483 Item 9]. For example, your firm reportedly discarded production rejects but did not maintain records of their disposition.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventative action on your quality system.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address. If you have any questions concerning this matter, you may contact Mr. Ta at (214) 253-5217.

Sincerely,

Michael A. Chappell
Dallas District Director

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